



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/948,149	10/09/1997	BRIAN M. FENDLY	P1053R2	6683

24510 7590 10/10/2003

PIPER MARBURY RUDNICK & WOLFE LLP  
STEVEN B KELBER  
1200 NINETEENTH STREET, NW  
WASHINGTON, DC 20036-2412

EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 10/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

08/948,149

Applicant(s)

FENDLY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25July2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 25July2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see Detailed Action.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.Claim(s) objected to: none.Claim(s) rejected: 28-40,42-62.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Art Unit: 1645

### DETAILED ACTION

1. Applicants' Response to Final Office Action, received 25 July 2003, paper #39, is acknowledged.
2. Currently, claims 28-40 and 42-62 are pending and under consideration.

### Rejections Maintained

3. The rejection of claims 28-31, 37-38, 40, 56, and 57 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991) is maintained for reasons of record.

Applicants argue that the antibodies utilized in the references are not publicly available due to the stringent requirements of the Materials Transfer Agreement of Genentech.

The examiner has considered applicants' arguments, but does not find them persuasive. Following discussions of the Materials Transfer Agreement with Brian Stanton, Quality Assurance Specialist, the MTA, while placing some restrictions on the use of the antibodies of Genentech, does not preclude anyone in the public from obtaining the materials as long as they agree to said restrictions. Therefore, the antibodies are deemed to be publicly available at the time of the filing of the instant application.

4. The rejection of claims 28-31, 37-38 and 40 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) is maintained for reasons of record.

Applicants argue that the antibodies utilized in the references are not publicly available due to the stringent requirements of the Materials Transfer Agreement of Genentech.

The examiner has considered applicants' arguments, but does not find them persuasive. Following discussions of the Materials Transfer Agreement with Brian Stanton, Quality

Art Unit: 1645

Assurance Specialist, the MTA, while placing some restrictions on the use of the antibodies of Genentech, does not preclude anyone in the public from obtaining the materials as long as they agree to said restrictions. Therefor, the antibodies are deemed to be publicly available at the time of the filing of the instant application.

5. The rejection of claims 32-36, 39, and 58 under 35 U.S.C. 103(a) as being unpatentable Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), or Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993), in view of Fendly et al (*Cancer Research*, 50:1550-1558, 1990), Deshane et al (*J. Invest. Med.*, 43(Suppl 2):328A, 1995), and further in view of Senter et al (U.S. Pat. No. 4,975,278) is maintained for reasons of record.

Applicants argue that that the antibodies utilized in the references are not publicly available due to the stringent requirements of the Materials Transfer Agreement of Genentech.

The examiner has considered applicants' arguments, but does not find them persuasive. Following discussions of the Materials Transfer Agreement with Brian Stanton, Quality Assurance Specialist, the MTA, while placing some restrictions on the use of the antibodies of Genentech, does not preclude anyone in the public from obtaining the materials as long as they agree to said restrictions. Therefor, the antibodies are deemed to be publicly available at the time of the filing of the instant application.

6. The rejection of claims 42-55 and 59-62 under 35 U.S.C. 103(a) as being unpatentable Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), in view of Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) and Fendly et al (*Cancer Research*, 50:1550-1558, 1990), and further in view of Deshane et al (*J. Invest. Med.*, 43(Suppl 2):328A, 1995) and Senter et al (U.S. Pat. No. 4,975,278) is maintained for reasons of record.

Art Unit: 1645

Applicants argue that the antibodies utilized in the references are not publicly available due to the stringent requirements of the Materials Transfer Agreement of Genentech.

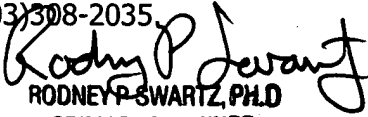
The examiner has considered applicants' arguments, but does not find them persuasive. Following discussions of the Materials Transfer Agreement with Brian Stanton, Quality Assurance Specialist, the MTA, while placing some restrictions on the use of the antibodies of Genentech, does not preclude anyone in the public from obtaining the materials as long as they agree to said restrictions. Therefore, the antibodies are deemed to be publicly available at the time of the filing of the instant application.

### Conclusion

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-2035.

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

October 9, 2003